

Amendments to the Drawings

The attached sheets of drawings include changes to Figs. 3, 4, and 6. These sheets, which include Figs. 1-8, replace the original sheets including Figs. 1-8. In Fig. 3, previously omitted element 112 has been added to correspond to the specification. See, e.g., paragraph 0039, lines 1-2 and 6-8. In Figure 4, mislabeled element 126 has been corrected to 120 to correspond to the specification. See, e.g., paragraph 0040, lines 2-4. In Figure 6, elements 120 and 218 have been switched to correspond to the specification. See, e.g., paragraph 0044, lines 3-5, and paragraph 45, lines 15.

Attachments: Replacements Sheet
Annotated Sheet Showing Changes

REMARKS/ARGUMENTS

The Applicants have amended the specification to correct typographical errors and to add a reference to the drawings (see amendment to paragraph 0027). The Applicants have also amended claims 17-19 to change the term "half" to the term "portion" and to correct inconsistencies between terminology in claims 17 and 19. The Applicants have also added new claim 21. Support for these amendments can be found throughout the originally-filed specification and drawings (see, e.g., paragraph 37, lines 6-10 and paragraph 42, lines 1-6). The Applicants have also amended Figures 3, 4, and 6 of the drawings. No new matter has been added.

The Examiner rejected claims 1-20 under 35 U.S.C. § 103(a) as being unpatentable over United States patent no. 4,938,220 issued to Mueller, Jr. (the "Mueller reference") in view of United States patent no. 6,562,049 issued to Norlander et al. (the "Norlander reference"). The Applicants respectfully traverse this rejection.

The present invention is directed to a splittable sheath having a radiopaque marker that is splittable along with the splittable sheath. Splittable sheaths are most useful during surgery when a device, such as a pacemaker lead, is left in a patient's body as the sheath is withdrawn. In such an operation it is desirable that the sheath split smoothly so that the lead is not damaged or moved as the sheath is withdrawn. In each of the independent claims (i.e., claims 1, 9, and 17), the sheath comprises a sheath body having a longitudinally-extending sheath score line, running substantially along a length of the sheath body, and a radiopaque marker abutting the sheath at a distal end of the sheath body.

Each of the independent claims provides at least one feature of the radiopaque marker (e.g., a score line, notch, or gap) to allow the radiopaque marker to split along with the splittable sheath.

In claim 1, for example, the radiopaque marker comprises a substantially cylindrical marker body having at least one longitudinally-extending marker score line running substantially along a length of the radiopaque marker.

In claim 9, the radiopaque marker comprises a substantially cylindrical marker body having at least one longitudinally-extending marker notch running substantially along a length of the radiopaque marker.

Claim 17, as amended, recites a first radiopaque marker comprising a first marker portion, wherein the radiopaque marker defines a gap substantially aligned with the sheath score line.

The dependent claims also provide, among other limitations, a second feature (e.g., another score line, notch, or gap) to allow the radiopaque marker to split into at least two separate portions along with the splittable sheath (see, e.g., claims 2-8, 10-16, and 19-21).

The Mueller reference discloses a radiopaque tip marker comprising a split sleeve of radiopaque material. The split sleeve is crimped about an inner tubular member, and an outer tubular member is bonded to the inner tubular member with the sleeve being captured between the two members. The split sleeve of the tip marker provides a gap 12 (see Fig. 2 of the Mueller reference) in which a vent passageway 24 of a balloon catheter extends to the distal end of the catheter and which allows the marker to be crimped about the inner tubular member. The Mueller reference does not disclose, teach, or suggest that the catheter or the radiopaque tip marker is splittable.

The Norlander reference discloses an introducer apparatus comprising a pair of co-extending splittable introducer sheaths that split along a predetermined split line. The reference discloses that radiopaque markings can be added to the distal end of the inner and/or outer introducer sheaths to augment visualization under fluoroscopy. In particular, the radiopacity can be achieved by incorporating radiopaque powders into the polymer sheath material or by adding a separate radiopaque marker such as a metal band, an annular ring of radiopaque paint, or other type of indicia affixed to or printed onto the introducer sheath.

“To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge that is generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the Applicants’ disclosure.” MPEP § 706.02(j) (citing In re Vaeck, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991)). The Applicants respectfully submit that the splittable sheaths of claims 1-20 are unique.

With respect to claims 1-8, for example, the radiopaque marker disclosed in the Mueller reference does not include a score line. The specification defines the term "score line" to "embrace scores, notches, serrations, walls having reduced cross-sections, and so forth." (See paragraph 0024, lines 7-9.) The marker disclosed by the Mueller reference, on the other hand, includes a gap (i.e., no radiopaque material for at least a longitudinally extending arcuate gap). The sheath of claims 1-8 comprises radiopaque material completely around the circumference of the marker, even if it is reduced at certain score line, notch, serration, or reduced cross-section wall locations. This allows the marker to be more easily seen at various angles when the sheath is located *in vivo*. The gap in the marker disclosed in the Mueller reference, however, completely eliminates the presence of radiopaque material along at least a longitudinally extending arcuate gap. The complete elimination of radiopaque material, for example, may make it more difficult for the marker to be seen at a particular angle when the sheath is located *in vivo*. The Mueller reference and the Norlander reference thus fail to teach or suggest a radiopaque marker having a score line as required by claims 1-8. Accordingly, the Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-8 and allow claims 1-8.

Claims 9-16 require a radiopaque marker comprising a substantially cylindrical marker body having at least one longitudinally extending marker notch running substantially along a length of the radiopaque marker. As described above with respect to claims 1-8, the radiopaque marker of claims 9-16 comprises radiopaque material extending completely around the circumference of the marker, even if it is reduced at the notch location. The radiopaque marker disclosed by the Mueller reference, however, comprises a marker having longitudinally extending arcuate gap that completely eliminates the presence of radiopaque material along that gap. The complete elimination of radiopaque material, for example, may make it more difficult for the marker to be seen at a particular angle when the sheath is located *in vivo*. Thus, the Mueller reference and the Norlander reference also fail to teach or suggest a radiopaque marker having a notch as required by claims 9-16. Accordingly, the Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 9-16 and allow claims 9-16.

Claims 17-21 require a first marker portion defining a gap that is substantially aligned with the sheath score line. Aligning the gap with the sheath score line provides the ability to more smoothly split the sheath and marker, which allows a surgeon to more easily remove a

sheath without moving or damaging a lead being left behind. While the Mueller reference discloses a radiopaque marker having a gap, neither the Mueller reference nor the Norlander reference teach or suggest aligning that gap with the sheath score line. The gap disclosed in the Mueller reference provides an opening for routing a vent from a balloon catheter to the distal tip of the catheter and further allows the marker to be crimped about an inner tubular member of the catheter. The Mueller reference does not teach or suggest that the gap provides an opening for allowing the catheter to be split or that this gap should be substantially aligned with a sheath score line. While the Norlander reference discloses that a separate marker may be used (see col. 3, lines 43-49), as opposed to incorporating a radiopaque powder into the sheath, the Norlander reference fails to teach or suggest that this separate marker should be splittable. Thus, neither the Mueller reference nor the Norlander reference provides a motivation to combine the references to achieve a splittable radiopaque marker having a gap aligned with a sheath score line, nor would the references, even if one skilled in the art were to combine them, teach or suggest the claimed invention of a splittable radiopaque marker having a gap aligned with a sheath score line. Accordingly, the Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 17-21 and allow claims 17-21.

In addition, dependent claims 2-8, 10-16, and 19-21 further require an additional feature (e.g., a second score line, notch, or gap) that allows the radiopaque marker to split into two separate portions. The radiopaque marker disclosed in the Mueller reference, however, is crimped about a catheter sheath and only has one gap. Adding a second gap in the Mueller marker would make it more difficult to crimp the marker about the sheath. Thus, the Mueller reference teaches away from the splittable sheaths of claims 2-8, 10-16, and 19-21. Accordingly, the Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 2-8, 10-16, and 19-21 and allow claims 2-8, 10-16, and 19-21 for these additional reasons, in addition to allowing the claims as depending directly or indirectly from an allowed independent claim.

CONCLUSION

Prior to entry of the above claim amendments, claims 1-20 were pending in the application. The Applicants have amended claims 17-19 and added new claim 21. No new matter has been added. The Applicants believe the pending claims are allowable and respectfully requests a timely Notice of Allowance be issued in this case. If the Examiner believes that a telephone conference may be helpful in resolving any remaining issues, the Examiner is invited to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted this 26th day of May 2005.



Thomas J. Osborne, Jr., Esq.
Registration No. 39,796
Customer No. 33486
HEIMBECHER & ASSOC., LLC
390 Union Boulevard, Suite 650
Lakewood, CO 80228-6512
TEL: (303) 279-8888
FAX: (303) 985-0651

Attachments

cc: Client
Docketing

FIG.4

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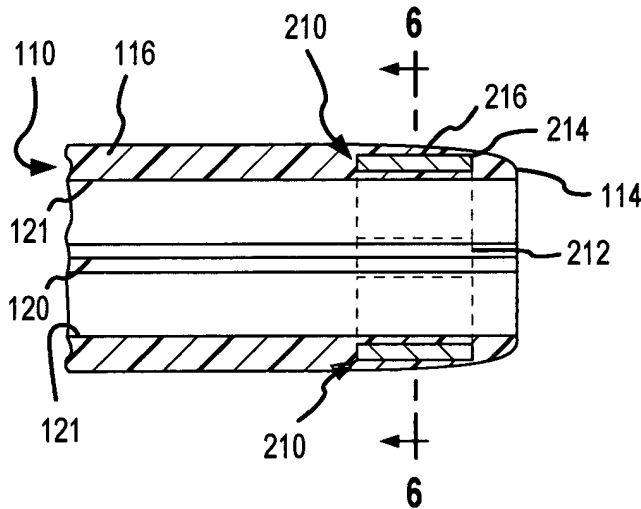


FIG. 5

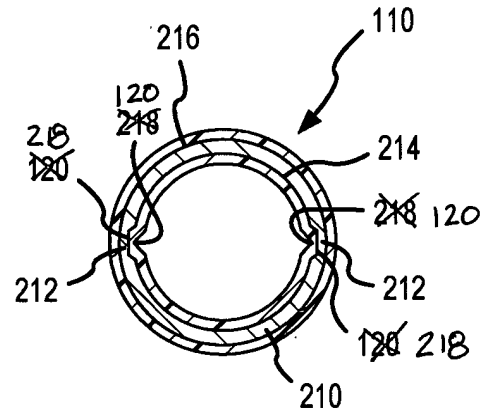


FIG. 6

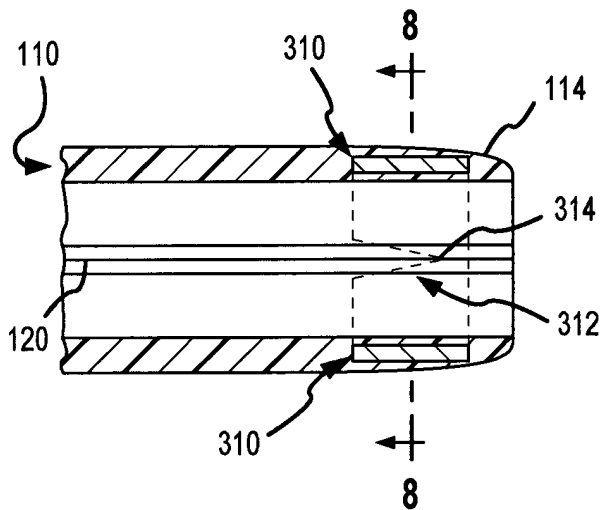


FIG. 7

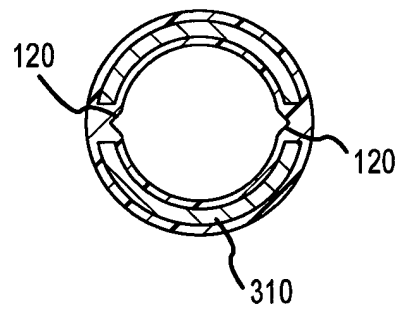


FIG. 8